

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: WAVE 3 CASES	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS’ REPLY IN SUPPORT OF MOTION TO
EXCLUDE THE OPINIONS AND TESTIMONY OF DUANE PRIDDY, PH.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, “Ethicon”) submit this Reply in Support of their Motion to Exclude the Opinions and Testimony of Duane Priddy, Ph.D. [Doc. 2843 (“Motion”)] and Memorandum of Law in Support [Doc. 2846 (“Mem.”)]. Ethicon requests that the Court grant its Motion and reject the arguments raised in Plaintiffs’ Response to the Motion [Doc. 2940 (“Response”)].

I. The Court Should Preclude Dr. Priddy’s Opinions Based On His OIT Testing Because It Was Conducted Under Conditions Unlike Anything Found In The Human Body.

In its Motion, Ethicon explained that Dr. Priddy should be precluded from offering opinions about the chemical or physical condition of Prolene used in the human body because his oxidative induction time (“OIT”) testing did not replicate *in vivo* conditions.¹ Mem. at 4-9. In

¹ Ethicon also showed that Dr. Priddy’s OIT testing is unreliable and speculative for the following reasons: (i) the express terms of his testing protocol state as much (Mem. at 9-11); (ii) Dr. Priddy failed to follow his own testing protocol without providing a scientific basis (*id.* at 11); (iii) Dr. Priddy failed to use a control and failed to determine whether his methodology introduced error into his test results (*id.* at 12-13); (iv) Dr. Priddy did not have a sufficient understanding of the basic details of the testing (*id.* at 13-14); and (v) Dr. Priddy did not provide any statistical analysis of his test data (*id.* at 14). Ethicon
(footnote cont’d)

fact, Ethicon showed that Dr. Priddy admitted under oath that his testing conditions—which were 300° F above the normal temperature of the human body with atmospheric conditions of 100% nitrogen and 100% oxygen—far exceed anything that pelvic mesh products could ever encounter in the human body. *Id.* at 6-7. For this reason, Ethicon argued that Dr. Priddy’s testing cannot constitute reliable scientific evidence as to the chemical or physical characteristics of Prolene used in the pelvic floor. *Id.* at 5-9.

In their Response, Plaintiffs claim that Ethicon has not “given the Court any reason” to issue a ruling different than its Wave 1 *Daubert* Order. Resp. at 2. But Ethicon has provided numerous decisions by the Fourth Circuit—as well as this Court’s rulings previously cited by Ethicon—holding that an expert should not be permitted to offer opinions based on testing conducted under conditions substantially different from those in which the product was used. *See* Mem. at 5-6.

Tellingly, Plaintiffs made no effort to distinguish any of these decisions. *See* Resp. at 1-2. Nor have Plaintiffs ever identified any case law or scientific support for the proposition that testing a product under circumstances bearing no relationship to those in which the product is actually used provides reliable or relevant evidence about the product’s condition or performance in its intended environment. *See id.*; *see also* Plfs.’ Resp. in Opp. to Ethicon’s Mot. to Exclude the Testimony of Duane Priddy, Ph.D., at 3-11 [Doc. 2168].

The Court has said that each motion must stand on its own foundation, and Ethicon has now provided the foundation for its distinction. Ethicon respectfully submits that the Court

respectfully submits that each of these reasons constitutes an independently valid basis for excluding Dr. Priddy’s testing.

should distinguish its prior ruling, and preclude Dr. Priddy from offering opinions based on this unreliable and irrelevant testing.²

II. The Court Should Exclude Dr. Priddy’s Degradation Opinions Because He Did Not Ground His Opinions In Relevant Scientific Literature.

Ethicon explained in its Motion that Dr. Priddy’s degradation opinions in this litigation are unreliable and irrelevant because they are based on articles that do not address the product at issue—Prolene—or are otherwise inapposite. Mem. at 14-17. Specifically, Ethicon identified all of the studies to which Dr. Priddy pointed as support for his opinion that the Prolene in Ethicon mesh products is subject to oxidative degradation in the pelvic floor. *See id.* Ethicon provided the Court with copies of these papers, and demonstrated that the papers on which Dr. Priddy relies to support his degradation opinions consist of the following:

- 11 articles that do not address Prolene at all;
- a review paper that addresses several articles that do not analyze Prolene at all, and three articles regarding ocular sutures (which are, by definition, exposed to ultraviolet radiation);
- an article regarding a hernia mesh classification system that does not address oxidation or degradation at all; and
- 3 papers by a pathologist functioning as a paid expert for Plaintiffs in pelvic mesh litigation, who did not conduct any of the analytical chemistry testing necessary to establish oxidative degradation and whose methodology has been debunked.

² Plaintiffs have challenged certain testing conducted by Dr. Shelby Thames on the grounds that his testing did not replicate the *in vivo* environment or incorporate a control. *See* Mem. of Law in Supp. of Plfs.’ Daubert Mot. to Exclude or Limit the Opinions and Testimony of Dr. Shelby Thames, at 2-5 [Doc. 2841]. As explained in Ethicon’s response to that challenge, Plaintiffs misunderstand the purpose and scope of Dr. Thames’s testing. *See* Resp. in Opp. to Plfs.’ Mot. to Exclude or Limit the Opinions and Testimony of Dr. Shelby Thames, at 6-7 [Doc. [2957]. Indeed, Dr. Thames’s testing was not intended to evaluate Prolene under *in vivo* conditions and he does not seek to opine about conditions in the human body based on that testing. *See id.* at 6. In stark contrast, Dr. Priddy seeks to offer opinions based on his testing about the *in vivo* condition and performance of Prolene. *See* Mot. Ex. F, Priddy Report at 3 (explaining that he conducted the OIT testing to “evaluate the performance of the antioxidant stabilizer in the Ethicon mesh samples and to predict the approximate time to oxidative degradation of the meshes[.]”).

See Mem. at 14-17. Ethicon submits that an expert's reliance on literature that does not actually provide support for his opinions renders the underlying opinions unreliable.

Plaintiffs' arguments in response do not actually address the substance of Ethicon's position, and should be rejected by this Court.

A. Dr. Priddy's failure to ground his opinions in relevant scientific literature demonstrates that his degradation opinions are unreliable, regardless of his testing.

In their Response, Plaintiffs attempt to re-frame Ethicon's position as an argument that the Court should only reach the question of whether Dr. Priddy's opinions are properly based on scientific literature if the Court excludes his opinions based on his testing. Resp. at 2. From this flawed premise, Plaintiffs claim that "Ethicon's argument is moot" because the Court previously admitted Dr. Priddy's OIT testing. *Id.*

As an initial matter, *Daubert* is not merely a sequential checklist of reliability factors courts must work through in succession, and Ethicon made no such argument in its Motion. Rather, Ethicon explained in its Motion that, without reliable testing to form a basis for his opinions, Dr. Priddy would have to provide another basis—namely, relevant scientific literature—for his opinions in order to satisfy *Daubert*. *See* Mem. at 2, 14.

In addition, even if this Court permits Dr. Priddy to testify based on his OIT testing—and it should not—the fact that he conducted his testing under such extreme conditions demonstrates that he must still establish a reliable foundation for any opinions he seeks to offer about the physical or chemical characteristics of Prolene that has been implanted in the human body. In other words, the Court should consider Dr. Priddy's failure to properly base his degradation opinions in relevant scientific literature regardless as to its ruling on Dr. Priddy's testing. Indeed, Plaintiffs' suggestion that Dr. Priddy should be able to offer all of his degradation opinions based

solely on his OIT testing highlights the need for the Court to reduce the likelihood of jury confusion by excluding Dr. Priddy's opinions regarding this testing.

B. Plaintiffs' experts have confirmed that Prolene is unique from other forms of polypropylene.

In its Motion, Ethicon explained that Plaintiffs' materials science experts—including Dr. Priddy—have admitted under oath that Prolene is chemically distinct from other forms of polypropylene, including commercially available formulations. *See* Mem. at 2-4 (quoting testimony by Dr. Priddy, as well as Plaintiffs other materials science experts, Dr. Jimmy Mays and Dr. Scott Guelcher). Specifically, Ethicon showed that Plaintiffs' materials scientists agreed that the singularity of Prolene is due to its unique additive package, including a proprietary blend of antioxidants that retard oxidation *in vivo*. *See id.* On this basis, Ethicon argued that Dr. Priddy's reliance on studies that do not involve Prolene renders his opinions about Prolene unreliable. *See id.* at 14-17.³

Notably, Plaintiffs did not address—much less dispute—the concessions made by their experts. *See generally* Pls.' Resp. in Opp. to Ethicon's Mot. to Exclude the Testimony of Duane Priddy, Ph.D. [Doc. 2940].

Instead, Plaintiffs simply argue that Dr. Priddy is not required to rely on scientific support addressing Prolene because the distinction between Prolene and other forms of polypropylene is a “lawyer-conceived argument [that] has consistently been rejected by this Court.” Resp. at 2-3 (citing *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 703 (S.D. W. Va. 2014)). Although Ethicon is certainly aware of the Court's prior orders, it nonetheless respectfully submits that a

³ Although Dr. Priddy also points to certain internal Ethicon documents to support his opinions, Ethicon explained in its Motion that tests on which Dr. Priddy relies simply do not support his opinion that the Prolene used in Ethicon mesh products is subject to scientifically significant oxidation or degradation in the human body. *See* Mem. at 18-19.

proposition to which Plaintiffs' materials science experts have agreed cannot be solely the product of Ethicon's attorneys' imaginations or divorced from the principles of science.

For the reasons stated above and in Ethicon's Motion, and in light of Plaintiffs failure to dispute or distinguish the testimony provided by their own experts, Ethicon requests that the Court distinguish its prior ruling.

C. Dr. Priddy cannot base his opinion that Prolene used in the human body is subject to oxidative degradation on the Mary study.

Plaintiffs seek to rebut Ethicon's arguments by claiming that Dr. Priddy actually does base his degradation opinions on scientific literature dealing with Prolene, and pointing to a single study in Dr. Priddy's reliance list by Celine Mary. Resp. at 3 (citing Resp. Ex. C, C. Mary, *et al.*, *Comparison of the In Vivo Behavior of Polyvinylidene Fluoride and Polypropylene Sutures Used in Vascular Surgery*, 44 Am. Soc'y Artificial Internal Organs J. 199 (1998)). But while Dr. Priddy cited to numerous papers in an attempt to support his degradation opinions, nowhere in his actual expert report or deposition did Dr. Priddy cite the Mary study. *See generally* Mot. Ex. F, Expert Report of Duane Priddy, Ph.D.; Mot. Ex. D, Priddy 3/8/16 Dep.

In addition, the Mary study simply does not furnish reliable support for Dr. Priddy's opinion that Prolene undergoes oxidative degradation *in vivo*. Notably, the Mary study authors did not test the mechanical properties of the sutures or conduct any molecular weight analysis, which Plaintiffs' other materials scientists have conceded is necessary to establish whether a polymer has undergone oxidative degradation. *See* Mot. Ex. E, Mays 3/2/16 Dep. 79:3-80:12 ("Q. But, Doctor, for oxidative degradation to occur, there must be loss of molecular weight, correct? A. Yes, when oxidative degradation occurs, there is degradation of molecular weight."); Mot. Ex. BB, Jordi 10/30/13 Dep. 173:25-174:8 (admitting that test results showing no loss of molecular weight suggests that there is no degradation of polypropylene).

Instead, the Mary study authors concluded that the Prolene sutures had oxidized based on FTIR test results showing a peak at $1,740\text{cm}^{-1}$, which “has been assigned to carbonyl stretching, and identifies the presence of surface oxidation, because the chemical structure of both pure polymers are devoid of this functional group.” Resp. Ex. C, Mary Study at 201. But the authors failed to recognize that $1,740\text{cm}^{-1}$ is also the wavelength for one of the antioxidants used in Prolene, a fact conceded by Plaintiffs’ other materials scientists. *See, e.g.*, Mot. Ex. E, Mays 3/2/16 Dep. 104:24–105:3 (admitting that one of the antioxidants used in Prolene has an FTIR signature of $1,740\text{cm}^{-1}$). Thus, the study failed to confirm that the peak at $1,740\text{cm}^{-1}$ was evidence of oxidation, rather than a reading of the antioxidant package used in Prolene.

In addition, the sample preparation process used in the Mary study introduced error into the SEM results. Specifically, the study explains that after explantation, the sutures designated for SEM analysis were treated with either formalin or gluteraldehyde prior to cleaning. Resp. Ex. C, Mary Study at 200. The study ignores the fact that both formalin and gluteraldehyde crosslink with the proteinaceous layer on the fibers to form a hardened shell that can manifest as a cracked layer under SEM. *See* Reply Ex. LL, Expert Report of Shelby Thames, at 10, 16–21 (explaining that fixatives used in sample preparation, such as formalin, bond or crosslink with proteins adhered to the surface of an explant to form a hard and brittle shell around the surface of the explant).

Although an expert can base his opinions on reliable scientific literature, the literature must actually stand for the proposition for which it is cited in order for the expert’s opinion to be considered reliable. The Mary study simply does not support the Dr. Priddy’s opinion that the Prolene used in Ethicon mesh products is subject to oxidative degradation.

D. The materials and methodologies used in the articles on which Dr. Priddy relies renders them inapposite.

Finally, Plaintiffs argue that Ethicon merely “disagree[s] with conclusions in the literature cited by Dr. Priddy.” Resp. at 3. Notably, Plaintiffs do not actually dispute the substance of Ethicon’s analysis of any of the papers on which Dr. Priddy relies. *See* Resp. at 3. Rather, Plaintiffs seek to muddy the waters by conflating the *methodology and materials* used in the articles with the *conclusions* drawn by the respective authors.

At no point in the Motion did Ethicon disagree with the conclusions of the studies on which Dr. Priddy relies. Mem. at 14-17. Rather, as discussed above and as Ethicon’s Motion makes clear, Ethicon’s position is that the studies on which Dr. Priddy relied either did not analyze Prolene or are otherwise inapposite. *See supra* at 3-7; Mem. at 14-17. And while Ethicon agrees that “the court’s focus must be solely on principles and methodology [the experts’ use] not on the conclusions they generate,” (Resp. at 3 n.9 (quotations and citation omitted)), Ethicon also states that an expert’s reliance on literature that does not address the substance at issue or contains known methodological flaws cannot be said to constitute legitimate scientific “principles and methodology.”

III. Dr. Priddy’s Reliance On Ethicon’s Internal Documents Is Misplaced.

In its Motion, Ethicon explained in detail why the internal Ethicon documents on which Dr. Priddy relies do not support his degradation opinions. Mot. at 18-19. Notably, Plaintiffs made no effort to respond to the substance of Ethicon’s arguments. Resp. at 3-4. The arguments Plaintiffs do offer, however, make no sense.

For instance, Plaintiffs claim that Dr. Priddy’s testimony is reliably based on Ethicon’s internal documents simply because Dr. Priddy stated in his expert report that the “results of these studies are consistent with my opinions in this case.” *See id.*; Mot. Ex. F, Priddy Report at 13-14. Dr. Priddy’s assertion is pure *ipse dixit*.

In addition, contrary to Plaintiffs' suggestion, it is of no moment that these documents have previously been admitted at trial or addressed by other experts. Resp. at 3. The question at issue is whether the documents provide a reliable basis for Dr. Priddy's opinions, not whether a document itself has been admitted or discussed in some other context. Because neither Dr. Priddy nor Plaintiffs have shown that these internal Ethicon documents actually support Dr. Priddy's opinions, the Court should exclude any opinions based on those documents as unreliable.

Finally, Plaintiffs claim that Ethicon's arguments amount to "nothing more than the description of a conflict in expert opinion and 'mere disagreement between experts is not, in itself, a reason to exclude an expert's testimony.'" *Id.* at 4. But Ethicon's arguments are not based on conflicting opinions offered by defense experts. *See* Mem. at 18-19. Rather, Ethicon merely offered a plain reading of the document itself and the proposition for which Dr. Priddy seeks to rely on the document. *See id.* Indeed, the only experts to whom Ethicon even refers are Plaintiffs other materials scientists, whose testimony demonstrates that Dr. Priddy's reliance on Ethicon's internal documents is misplaced. *See id.*

IV. Conclusion

For all of these reasons, as well as those set forth in Ethicon's Motion, Ethicon respectfully requests that the Court grant its Motion to Exclude the Testimony of Dr. Duane Priddy.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on October 21, 2016, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

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